REMARKS

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner indicates that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. More specifically, the Examiner states that the claims set forth the treatment of all the conditions of the central nervous system but the specification indicates that gabapentin is a neuroleptic agent as adjunctive therapy in the treatment of central nervous system conditions in mammalian subjects, such as partial seizures, epilepsy, faintness attached, hypokinesis, pain associated with shingles, and cranial trauma. The Examiner then listed a series of central nervous system diseases which included, for example, Alzheimer Disease, Cerebral Palsy, Parkinson Disease, and Spinal Cord Diseases.

In response to the above rejection by the Examiner, Applicants have amended claims 1, 4, 6 and 7 by deleting the phrase "for treating a condition of the central nervous system in a mammalian subject." Claims 1, 4, 6 and 7 now define the invention as a pharmaceutical composition of gabapentin tannate containing a pharmaceutically effective amount of gabapentin tannate in a solid dosage form.

Throughout the specification, Applicants have defined the invention as being a pharmaceutical composition containing a pharmaceutically effective amount of gabapentin tannate in a solid dosage form and the process for making the gabapentin tannate. Claims 1, 4, 6 and 7, as amended, are consistent with the disclosed invention in the specification.

Claim 17 has been amended to include only the CNS disorders disclosed in the specification for which gabapentin has been shown to be therapeutically effective.

The Examiner indicates that the nature of the invention in claims 1, 4, 6, 11, and 17 is the method of treating a condition of the central nervous system in a mammalian subject by administering gabapentin. Claims 1, 4, 6, 11, and 17 have been amended to more clearly define the invention as being a process for preparing a gabapentin tannate pharmaceutical composition, a gabapentin tannate pharmaceutical composition and a method for treating those conditions of the central nervous system that are set forth in the specification as being known to be effectively treated by gabapentin. The specification and the amended claims clearly define the invention as being the formation of a tannate salt of gabapentin. Furthermore, such a combination is unexpected because of the close proximity of a carboxylic acid group to the amine group in the gabapentin chemical structure. The negative charge on the carboxylic acid group was expected to shield and possibly neutralize the positive charge on the proximal nitrogen. Since tannate salts are thought to not only form through an ionic interaction with a positively charged amine functional group, the close proximity of the carboxylic acid group was expected to prevent the formation of the tannate salt. Thus, the preparation of gabapentin tannate was an unexpected and surprising result.

Claims 1, 4, 6 and 7 now define the invention as being the gabapentin tannate pharmaceutical composition and process for making the gabapentin tannate. Applicant asserts that the rejection of claims 1, 4, 6 and 7 based on the use of gabapentin for the treatment of all the CNS diseases has been overcome. Specifically, the Examiner's rejections were based on the lack of direction and guidance for the role of gabapentin for

the treatment of all CNS diseases, the lack of working examples for all the CNS diseases, the breadth of the claims to include that gabapentin can treat any condition of the CNS system in a mammalian subject, the quantity of experimentation needed to determine what CNS diseases would be benefited, and the unpredictability in the pharmaceutical art in determining which one of the CNS diseases would benefit from this activity. The foregoing rejections have been overcome with the amendments effected in the pending claims.

Claim 17, which is the only claim that relates to a method of treatment, specifically recites the known conditions for which gabapentin has been shown to be effective.

Based on the amendments to the claims and the above Remarks, Applicants believe that the pending claims are in condition for allowance. Accordingly, such action is earnestly solicited.

Respectfully submitted,

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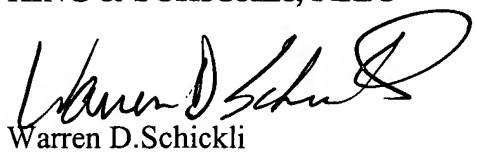

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